Complete Summary

GUIDELINE TITLE

Newborn screening for cystic fibrosis: evaluation of benefits and risks and recommendations for state newborn screening programs.

BIBLIOGRAPHIC SOURCE(S)

Grosse SD, Boyle CA, Botkin JR, Comeau AM, Kharrazi M, Rosenfeld M, Wilfond BS. Newborn screening for cystic fibrosis: evaluation of benefits and risks and recommendations for state newborn screening programs. MMWR Recomm Rep 2004 Oct 15;53(RR-13):1-36. [154 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cystic fibrosis

GUIDELINE CATEGORY

Counseling
Diagnosis
Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Infectious Diseases
Nutrition
Obstetrics and Gynecology
Pediatrics
Pulmonary Medicine

INTENDED USERS

Health Care Providers
Hospitals
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To review and evaluate the scientific evidence on benefits and risks of newborn screening for cystic fibrosis (CF)
- To review screening, diagnostics, and follow-up concerns in CF newborn screening decision making
- To disseminate information about models and best practices for states that choose to adopt newborn screening for CF
- To advise states that choose to adopt newborn screening for CF on how to maximize benefits and minimize harms in implementing screening

TARGET POPULATION

Newborn infants

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Diagnosis/Assessment

1. Prenatal screening for cystic fibrosis (CF)
2. Newborn screening for CF
    - Immunoreactive trypsinogen (IRT) levels
    - IRT-repeat IRT protocols
    - IRT-DNA analysis (deltaF508, multiple mutations)
3. Meconium albumin levels
4. Sweat chloride test
5. High resolution chest tomography
6. Measurement of anthropometric indicators
7. Spirometric measures of lung function

Other Practices/Monitoring

1. Obtaining parental consent for newborn screening
2. Minimization of time delays between informing parents of positive results and providing sweat tests

3. Provision of psychological support for the families of infants with CF and for CF carriers
4. Infection control practices during screening processes
5. Referral of patients to specialized CF centers for optimal treatment
6. Regular microbiologic monitoring
7. Use of comprehensive communications plans, effective risk communication strategies and assessment of parental understanding of routine screening programs

MAJOR OUTCOMES CONSIDERED

- Analytical and clinical validity of cystic fibrosis screening tests (rate of false-positive and false-negative results)
- Disease-oriented outcomes, including nutritional and pulmonary outcomes (e.g., height/weight, spirometric measures of lung function, chest radiograph scores, respiratory microbiology)
- Patient-oriented outcomes (e.g., survival, quality of life, costs of hospitalization and therapies, cognitive function)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Patient Registry Data
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In preparation for the workshop, the Center for Disease Control (CDC) searched the MEDLINE® database of medical literature for articles on newborn screening for cystic fibrosis (CF) published since the 1997 workshop that discussed health outcomes or psychosocial outcomes in groups of children identified with CF through newborn screening in comparison with children identified through other means. In addition, review articles were obtained and reference lists searched to identify additional articles. Subsequently, a decision was made to include findings from previously published studies, which were identified by searches of reference lists.

An analytic framework was developed that modeled indirect links from newborn screening to nutritional status and from nutritional status to lung function and survival (See figure in original document). Accordingly, a literature search was also conducted to locate studies of associations between nutritional status among children and adolescents with CF and lung function or survival outcomes. This search used the MEDLINE® database and soliciting of specialists for additional studies.

A planning committee for the workshop identified researchers worldwide examining outcomes in relation to newborn screening for CF. At least one person

from each research study group was invited to present the study's findings at the 2003 workshop. Certain presentations were based on research that had already been accepted for publication or was in press. In addition, the Cystic Fibrosis Foundation (CFF) decided to cosponsor a peer-reviewed supplement to the Journal of Pediatrics to which presenters were invited to submit papers for publication; 15 papers cited in this report are scheduled for publication in that supplement.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

	Type of Study		
Study quality	Diagnosis	Treatment/Prevention/ Screening	Prognosis
Level 1: high-quality patient-oriented evidence	• Validated clinical decision rule • Systematic review (SR)/ meta-analysis of high quality studies • High-quality diagnostic cohort study[1]	• SR/meta-analysis of randomized control trials (RCTs) with consistent findings • High-quality individual RCT[2] • All or none study[3]	• SR/meta-analysis of high-quality cohort studies • Prospective cohort study with good follow-up
Level 2: limited-quality patient-oriented evidence	• Unvalidated clinical decision rule • SR/meta-analysis of lower quality	• SR/meta-analysis of lower quality clinical trials or studies with inconsistent findings • Lower-quality clinical trial	• SR/meta-analysis of lower-quality cohort studies or studies with inconsistent results

	Type of Study		
Study quality	Diagnosis	Treatment/Prevention/ Screening	Prognosis
	studies or studies with inconsistent findings • Lower-quality diagnostic cohort study or diagnostic case-control study	• Cohort study • Case-control study	• Retrospective cohort study or prospective cohort study with poor follow-up • Case-control study • Case series
Level 3: other evidence	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), and case series for studies of diagnosis, treatment, prevention, or screening		
Consistency Across Studies			
Consistent	• Majority of studies reported similar or at least coherent conclusions (i.e., differences are explainable), or • If high-quality and up-to-date systematic reviews or meta-analyses exist, they support the recommendation.		
Inconsistent	• Considerable variation among study findings and lack of coherence, or • If high-quality and up-to-date systematic reviews or meta-analyses exist, they do not find consistent evidence in favor of the recommendation.		

[1] That is, cohort design, adequate size, adequate spectrum of patients, blinding, and a consistent, well-defined reference standard.

[2]Allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, and adequate follow-up (i.e., >80%).

[3]One in which the treatment causes a dramatic change in outcomes (e.g., antibiotics, meningitis, or surgery for appendicitis) that precludes study in a controlled trial.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Analytic Framework for Evaluating Effects of Cystic Fibrosis (CF) Newborn Screening

To evaluate the potential benefits and risks of newborn screening for CF, the Centers for Disease Control and Prevention (CDC) applied an analytic framework to interpret evidence of clinical utility (i.e., the net balance of health outcomes) of earlier identification and treatment (see figure in the original guideline document). This framework draws in part on the approach used by the U.S. Preventive Services Task Force (USPSTF). It considers both potential benefits and harms from screening; harms are classified separately as adverse effects from screening and those from diagnosis or treatment. The benefits of screening flow from early, asymptomatic detection and can be classified in terms of health benefits to the affected person and psychosocial benefits to persons and families. To classify health benefits, CDC used the Strength of Recommendations Taxonomy (SORT), a recently proposed patient-centered approach to grading evidence in medical literature (See "Rating Scheme for the Strength of the Recommendations" and "Rating Scheme for the Strength of the Evidence.") The SORT framework does not include psychosocial outcomes, which constitute key benefits and risks from newborn screening for CF and should be considered in policy recommendations.

The potential psychosocial risks of screening include factors associated with 1) false-positives (e.g., unnecessary testing and possibly unnecessary treatment for the child, undue parental anxiety, and desensitization of providers), 2) false-negatives (e.g., potential delay in diagnosis for child and false reassurance for patients), 3) carrier reporting (e.g., possibly unwanted information and fear of stigmatization or insurance discrimination), and 4) misinformation (e.g., errors in communication or misunderstanding of results). Potential harms to CF patients of early detection and treatment as a result of newborn screening include side effects of therapies (e.g., drug resistance and toxicities) and earlier exposure (through person-to-person transmission from older children with CF) to bacteria associated with chronic airway infection in CF.

The SORT taxonomy is used to assess the clinical effectiveness of interventions based on a structured review of research findings. The SORT framework categorizes studies into three levels (Levels 1, 2, and 3) on the basis of study design and type of outcomes assessed. The total evidence for an intervention is given one of three grades (A, B, or C) on the basis of the assigned levels of the individual studies.

The SORT taxonomy distinguishes two classes of health outcomes: 1) disease-oriented outcomes (e.g., intermediate, histopathologic, physiologic, or surrogate results) that might reflect improvements in patient outcomes and 2) patient-

oriented outcomes (e.g., reduced morbidity, reduced mortality, symptom improvement, improved quality of life, or lower cost) that help patients live longer or better lives.

In the SORT framework, either a high-quality randomized controlled trial (RCT) or a meta-analysis of RCTs that demonstrates improved patient-oriented outcomes is considered Level-1 evidence. Information on patient-oriented outcomes from a lower-quality clinical trial, cohort study, or case-control study constitutes Level-2 evidence. All other types of research studies, including case series, are classified as Level 3, along with all studies, even RCTs, that provide information restricted to disease-oriented outcomes.

For the SORT framework to be applied, endpoints used in evaluations of newborn screening for CF are classified as either patient-oriented or disease-oriented. The approach taken in this report is to classify endpoints that are collected during routine clinical monitoring of individuals with CF as disease-oriented outcomes. These include measures of nutritional and pulmonary outcomes (e.g., height and weight, spirometric measures of lung function, and chest radiograph scores). In this analysis, survival, quality of life, and cost (including hospitalizations and invasive therapies) were classified as patient-oriented outcomes. Cognitive function, which is not routinely assessed in persons with CF, was also classified as a patient-oriented outcome because of its direct link to quality of life and because it is not a surrogate outcome in CF. The classification of certain endpoints as disease-oriented or patient-oriented outcomes has implications for assessment of evidence on newborn screening for CF. In particular, growth retardation might be regarded as both a patient-oriented outcome and a disease-oriented outcome. The high demand for expensive growth hormone therapy, which results in moderate gains in linear growth for children with CF who have low height-for- age , indicates that below-normal stature might be viewed as a patient-oriented outcome. In addition, growth retardation among children with CF has been demonstrated to be a strong predictor of survival. An RCT indicating reduction in growth retardation would be classified as Level-1 evidence if this outcome were classified as patient-oriented but as Level-3 evidence if it were classified as disease-oriented.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In 1997, the Centers for Disease Control and Prevention (CDC) convened a workshop that reviewed the state of scientific evidence on newborn screening for cystic fibrosis (CF) and formulated recommendations. At that time, newborn screening for CF was conducted in those three states and in three other states (Connecticut, Montana, and Pennsylvania) in which certain hospitals provided screening for CF as a clinical service.

Participants in the 1997 workshop found sufficient evidence of nutritional benefit to recommend state-based demonstration screening projects. Because evidence regarding pulmonary or other outcomes was limited, newborn screening for CF

was recommended for research purposes, with informed consent and protocols for tracking and evaluating outcomes. Research was to focus on 1) the consequences of delayed diagnosis, 2) cognitive development caused by malnutrition, 3) pulmonary benefits, and 4) the cost-effectiveness of early detection through screening. A subsequent workshop was to be held to evaluate new evidence and, if warranted, to revise recommendations relating to newborn screening for CF.

In November 2003, in cooperation with the Cystic Fibrosis Foundation (CFF), CDC held a second workshop in Atlanta, Georgia. This workshop had three objectives: 1) to review and evaluate the scientific evidence on benefits and risks of newborn screening for CF; 2) to review screening, diagnostics, and follow-up concerns in CF newborn screening decision making; and 3) to disseminate information about models and best practices for states that choose to adopt newborn screening for CF. The workshop was announced in the Federal Register, and the proceedings are available online (http://www.cdc.gov/ncbddd/cf/meeting.htm). In addition, the majority of the papers presented at the workshop will be published in a CFF-sponsored supplement to the Journal of Pediatrics.

Strength of Recommendations Taxonomy

The Strength of Recommendations Taxonomy (SORT) approach integrates the strength of evidence approach with the type of health outcomes considered in establishing a hierarchy of evidence In the SORT taxonomy, an A-level recommendation requires consistent and high-quality, patient-oriented evidence, including consistent findings from at least two high-quality randomized controlled trials. A B-level recommendation requires patient-oriented evidence (i.e., an improvement in morbidity, mortality, symptoms, quality of life, or cost) based on Level-1 or Level-2 evidence. A C-level recommendation is based on evidence relating to disease-oriented outcomes from any type of study or for patient-oriented outcomes from other types of observational studies, case series, or opinions of specialists. A limitation of the SORT framework for evaluating the overall strength of evidence for newborn screening tests is the scarcity of RCTs. CF is the only condition for which two RCTs of newborn screening have been conducted. This puts newborn screening at a disadvantage, with a B-level recommendation realistically the highest that can be assigned to any newborn screening test by using this framework.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Level A: Recommendation based on consistent and good-quality patient-oriented evidence*

Level B: Recommendation based on inconsistent or limited-quality patient-oriented evidence

Level C: Recommendation based on consensus, usual practice, opinion, disease-oriented evidence,** and case series for studies of diagnosis, treatment, prevention, or screening

* Measures outcomes that matter to patients: morbidity, mortality, symptom improvement, cost reduction, or quality of life.

** Measures intermediate, physiologic, or surrogate endpoints that might reflect improvements in patient outcomes (e.g., blood pressure, blood chemistry, physiologic function, and pathologic findings)

COST ANALYSIS

A full cost-effectiveness analysis of the costs and benefits of newborn screening has not been conducted. Partial cost analyses conducted in Wisconsin indicated that the majority of cystic fibrosis (CF) screening costs in that state were offset by savings from the reduction in the ordering of sweat tests.

Other potential economic benefits are reductions in hospitalizations and medications for screened children that have been reported, although not in the Wisconsin study. Indeed, one of the major benefits of newborn screening for CF might be to reduce the level of treatments and costs needed to maintain comparable health status between screened and unscreened children. In the absence of formal economic evaluations, states should assess the economic benefits of newborn screening for CF compared with other alternative actions that might be foregone if resources were allocated to CF screening (e.g., adding another disorder to newborn screening panels).

Data from the Wisconsin screening program indicate that the laboratory cost of immunoreactive trypsinogen (IRT) screening is $1.50/test, the cost of a single-mutation analysis is $20.50, and the cost of a multiple-mutation test is $50.70 (68). These numbers yield average costs of $2.35 for an IRT/DNA algorithm with a single mutation and $3.60 for an IRT/DNA algorithm with a multiple-mutation panel. A full accounting of the costs of implementing newborn screening for CF would require additional information on the costs of follow-up, diagnosis, counseling, and providing care. In addition, averted diagnostic and treatment costs, if any, should be factored in. A preliminary analysis indicates that averted diagnostic costs could cover the majority of initial screening costs.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

On the basis of the SORT taxonomy (see definitions at the end of the "Major Recommendations" field) as applied in this report, the evidence of health benefits merits a B-level recommendation for newborn screening for cystic fibrosis (CF).

The magnitude of the health benefits from screening for CF is sufficient that states should consider including routine newborn screening for CF in conjunction with systems to ensure access to high-quality care.

- In reaching a decision as to whether to add newborn screening for CF, states should consider available state resources and priorities as well as available national guidelines regarding CF screening, diagnosis, and treatment.
- States that implement newborn screening for CF should collect follow-up data in collaboration with CF care centers and analyze this information to monitor and improve the quality of CF newborn screening. In particular, states should collect, share, and analyze data by using standard protocols to evaluate and optimize laboratory algorithms used to screen for CF and refer for diagnosis. States seeking guidance on optimal laboratory protocols might wish to consult with states having more experience in conducting CF screening of newborns.
- Newborn screening for CF should be accompanied by rigorous infection control practices to minimize the risk to children with CF detected at an early age of acquiring infectious organisms associated with lung disease from older patients. Further research is needed to evaluate and optimize these practices.
- Newborn screening systems should ensure parental and provider education and communication of screening results to primary-care providers in a manner that will ensure prompt referral to diagnostic centers. For CF, these should be centers skilled in providing both sweat tests to young, presymptomatic children with CF and accurate and effective counseling to families, including those with infants identified as carriers. States are recommended to work with each other and with professional organizations and federal agencies to develop approaches to provide newborn screening information to parents during the prenatal and perinatal periods on all conditions, including CF, to facilitate informed choices and appropriate responses to positive screen results.

Definitions

Rating Scheme for Strength of Recommendations

Level A: Recommendation based on consistent and good-quality patient-oriented evidence*

Level B: Recommendation based on inconsistent or limited-quality patient-oriented evidence

Level C: Recommendation based on consensus, usual practice, opinion, disease-oriented evidence,** and case series for studies of diagnosis, treatment, prevention, or screening

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** Measures intermediate, physiologic, or surrogate endpoints that might reflect improvements in patient outcomes (e.g., blood pressure, blood chemistry, physiologic function, and pathologic findings)

Rating Scheme for the Strength of the Evidence

	Type of Study

Study quality	Diagnosis	Treatment/Prevention/ Screening	Prognosis
Level 1: high-quality patient-oriented evidence	• Validated clinical decision rule • Systematic review (SR)/ meta-analysis of high quality studies • High-quality diagnostic cohort study[1]	• SR/meta-analysis of randomized control trials (RCTs) with consistent findings • High-quality individual RCT[2] • All or none study[3]	• SR/meta-analysis of high-quality cohort studies • Prospective cohort study with good follow-up
Level 2: limited-quality patient-oriented evidence	• Unvalidated clinical decision rule • SR/meta-analysis of lower quality studies or studies with inconsistent findings • Lower-quality diagnostic cohort study or diagnostic case-control study	• SR/meta-analysis of lower quality clinical trials or studies with inconsistent findings • Lower-quality clinical trial • Cohort study • Case-control study	• SR/meta-analysis of lower-quality cohort studies or studies with inconsistent results • Retrospective cohort study or prospective cohort study with poor follow-up • Case-control study • Case series
Level 3: other evidence	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), and case series for studies of diagnosis, treatment, prevention, or screening		

	Type of Study		
Study quality	Diagnosis	Treatment/Prevention/ Screening	Prognosis
Consistency Across Studies			
Consistent	• Majority of studies reported similar or at least coherent conclusions (i.e., differences are explainable), or • If high-quality and up-to-date systematic reviews or meta-analyses exist, they support the recommendation.		
Inconsistent	• Considerable variation among study findings and lack of coherence, or • If high-quality and up-to-date systematic reviews or meta-analyses exist, they do not find consistent evidence in favor of the recommendation.		

[1] That is, cohort design, adequate size, adequate spectrum of patients, blinding, and a consistent, well-defined reference standard.

[2]Allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, and adequate follow-up (i.e., >80%).

[3]One in which the treatment causes a dramatic change in outcomes (e.g., antibiotics, meningitis, or surgery for appendicitis) that precludes study in a controlled trial.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for the recommendation for newborn screening for cystic fibrosis (see "Major Recommendations").

This recommendation includes consistent Level-2 evidence for improved child survival, although not all studies find statistically significant differences. Although Level-2 evidence of benefit in terms of reduced hospitalizations has also been reported from multiple studies, the Wisconsin randomized controlled trial (RCT) provided inconsistent findings. One high-quality RCT has yielded positive findings for two outcomes, growth and cognitive ability. Level-1 evidence for cognitive outcome supports a B-level recommendation. If impaired growth were classified

as a patient-oriented outcome, Level-1 evidence from the Wisconsin RCT and Level-2 evidence from several observational studies would also provide support for a B-level recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Demonstrated long-term benefits from early nutritional treatment as a result of newborn screening for cystic fibrosis include improved growth and, in one study, cognitive development. Other benefits might include reduced hospitalizations and improved survival. Mixed evidence has been reported for pulmonary outcomes. Newborn screening in the United States is associated with diagnosis of cystic fibrosis a median of 1 year earlier than symptomatic detection, which might reduce the expense and anxiety associated with work-up for failure to thrive or other symptoms.

POTENTIAL HARMS

- Possibility of parental distress, anxiety and disturbance of the parent-child bond caused by awaiting the results of CF screening
- Confusion regarding the implications of CF carrier status
- False-positive CF screening test result, which may result in parental anxiety and increase in the number of referrals for sweat tests or genetic counseling and overburdening of the healthcare system
- False-negative CF screening test result, which may result in delayed diagnosis, parental anxiety, and increased health risks to the infant
- Possibility of potential stigmatization and discrimination based on CF carrier status

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This report summarizes what is known about the strength of evidence for health benefits of newborn screening for cystic fibrosis (CF), including assessments of the strengths and limitations of study designs and the consistency and magnitude of benefits reported. However, the report is not a formal systematic evidence review that would form the basis for an evidence-based practice guideline. Systematic reviews involve a lengthy process in which teams of reviewers conduct structured reviews with blinded assessments of study quality. The only newborn screening tests endorsed by United States Preventive Services Task Force (USPSTF) on the basis of systematic reviews are for phenylketonuria (PKU), congenital hypothyroidism, and hemoglobinopathies.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The net balance of benefits and risks is contingent on how newborn screening for cystic fibrosis (CF) is implemented. Consequently, newborn screening programs for CF, if initiated, should be of high quality and carefully monitored to ensure consistent quality and effectiveness. CF screening programs are complex and should be developed in a deliberate fashion with attention to the experience of existing programs. Benefits are likely to be maximized if children have access to state-of-the-art therapy and follow-up with experienced professionals. Adoption of newborn screening for CF should be accompanied by an implementation planning process involving specialized CF care centers and specialists in risk communication, including genetic counselors. An implementation plan should ensure that adequate personnel and other resources required for the accurate diagnosis and clinical management of young children with CF and the psychosocial and genetic counseling needs of families with screen-positive infants are made available to ensure effective and equitable access to services.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Grosse SD, Boyle CA, Botkin JR, Comeau AM, Kharrazi M, Rosenfeld M, Wilfond BS. Newborn screening for cystic fibrosis: evaluation of benefits and risks and recommendations for state newborn screening programs. MMWR Recomm Rep 2004 Oct 15;53(RR-13):1-36. [154 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Oct 15

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The Centers for Disease Control and Prevention (CDC), their planners, and their content specialists wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters with the exception of Anne Marie Comeau, Ph.D. She wishes to disclose that she is employed by the University of Massachusetts Medical School, which operates a newborn screening program. This report does not include any discussion of the unlabeled use of a product or a product under investigational use.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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